

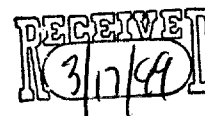


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1302 '99 MAR 23 P2:16

March 15, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Valerian Root Complex: For restful well-being. Valerian's calming properties have long been known in Europe where it is used to soothe tension and restlessness, and enhance serene, restful sleep. To further support restful well-being, take Sundown Valerian Complex with Sundown B Complex and Sundown Magnesium. The B vitamins are essential for a normal functioning nervous system and may also be helpful for stress management. Magnesium is an essential trace mineral that supports muscle relaxation. Sundown Herbal Complex formulas are carefully selected herbal combinations that naturally promote well-being. Valerian, an aromatic flowering plant, has been prized since ancient Roman times for its calming and rest-promoting properties. In Sundown Valerian Complex, Valerian, Kava Kava, and Passionflower are selectively combined to help support restful well-being.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

97S-0162

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